

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters) MD-15-02641-PHX-DGC
Products Liability Litigation)
) Phoenix, Arizona
) May 18, 2018
)
Doris Jones, an individual,)
)
Plaintiff,)
) CV-16-00782-PHX-DGC
v.)
)
C.R. Bard, Inc., a New Jersey)
corporation; and Bard Peripheral)
Vascular, Inc., an Arizona)
corporation,)
)
Defendants.)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 4 - P.M. SESSION

(Pages 862 - 934)

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DIRECT EXAMINATION (CONT'D) - BRET BAIRD

P R O C E E D I N G S

(Proceedings resumed in open court with the jury present.)

THE COURT: Ladies and gentlemen, for your information, we're going to go to 4:15 today. That's when we'll break.

Mr. Clark.

MR. CLARK: May we proceed with the direct examination of Mr. Baird?

THE COURT: You may.

BRET BAIRD,

recalled as a witness herein, after having been previously sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

BY MR. CLARK:

Q Welcome back, Mr. Baird. Hope you had a good lunch.

A Thank you. Yes.

MR. CLARK: Can you pull up, Gay, 1788, please.

And please go to page 4.

Your Honor, may I publish this to the jury?

THE COURT: You may.

MR. CLARK: If you could highlight Value Proposition, the first paragraph.

That's fine.

DIRECT EXAMINATION (CONT'D) - BRET BAIRD

13:01:47 1 BY MR. CLARK:

2 Q Sir, we were talking a little bit about the hope that the
3 Meridian with the additional caudal anchors would address the
4 issue of caudal migration. Do you remember that?

13:01:58 5 A Correct.

6 Q And it says here that the theory would be that the
7 addition of caudal anchors should limit the amount of tilt
8 which may in turn reduce the likelihood of penetration and
9 fracture.

13:02:14 10 Was that the hope for this project?

11 A That's the hope for this project; correct.

12 Q Now, are you aware of any time while you were at Bard of
13 Bard telling doctors about this cascade of problems that could
14 result from caudal migration?

13:02:26 15 A I don't recall having a conversation.

16 Q Are you aware of any time where Bard told physicians that
17 it might want to consider not using the Eclipse because
18 another product was coming on line that would address caudal
19 migration and this other cascade of issues?

13:02:42 20 A No, I don't recall.

21 Q Are you aware of Bard telling physicians that it was going
22 to be -- that -- strike that. Let me withdraw the question.

23 In 2009, there were plans made to have not only the
24 Eclipse, but also segueing into the Meridian and later the
13:03:02 25 Denali; correct?

DIRECT EXAMINATION (CONT'D) - BRET BAIRD

13:03:04 1 A I don't know which documents and what timing with R&D.

2 MR. CLARK: Could you please pull up 591, Gay.

3 May I publish this to the jury, Your Honor?

4 THE COURT: Yes.

13:03:26 5 BY MR. CLARK:

6 Q Mr. Baird, we've seen this before. This is the Idea POA
7 for the Denali?

8 A Yes.

9 Q And the date on that is?

13:03:34 10 A August 2009.

11 Q So as of August 2009, there were already plans in the
12 works to have a filter come on the market that would have
13 design features such as penetration limiters and caudal
14 anchors and other safety features that would help it be
15 self-centering; right?

16 A That's a potential early on in the project.

17 Q To your knowledge, did Bard ever tell doctors that they
18 should wait before they consider using the Eclipse until
19 another filter like this came on line?

13:04:07 20 A Not to my knowledge.

21 Q Did they ever tell doctors they believed they had a filter
22 prototype that could address these issues?

23 A I don't know.

24 MR. CLARK: Your Honor, at this time I move for
13:04:27 25 admissibility of Exhibit 587.

DIRECT EXAMINATION (CONT'D) - BRET BAIRD

13:04:29 1 THE COURT: Which one is that?

2 MR. CLARK: This is the Dr. Nicholson exhibit.

3 THE COURT: All right.

4 MR. CLARK: I would offer it with the caveat that we
13:04:37 5 are not offering it for the truth of the matter asserted, but
6 merely to show what Bard was reacting to.

7 THE COURT: All right.

8 MS. HELM: Your Honor, no objection subject to an
9 instruction from the Court.

13:04:47 10 THE COURT: All right.

11 Ladies and gentlemen, under the rules of evidence I'm
12 going to admit this document. It's the article written by
13 Dr. Nicholson. In considering the document, however, because
14 of the rules of evidence, you should not consider it for the
13:05:02 15 truth of what Dr. Nicholson was saying. In other words, don't
16 consider it to establish the truth of the facts he's setting
17 forth.

18 The reason it's being admitted is so that you can
19 understand what Bard knew about what Nicholson said. So it
13:05:17 20 goes to Bard's knowledge that it knew there was this article
21 out there with the contents. That's the relevancy, not the
22 truth of the matter actually asserted in the article.

23 (Exhibit 587 admitted.)

24 MR. CLARK: May I publish, Your Honor?

13:05:33 25 THE COURT: You may.

DIRECT EXAMINATION (CONT'D) - BRET BAIRD

13:05:33 1 MR. CLARK: Gay, could you please blow up -- thank
2 you; you read my mind.

3 BY MR. CLARK:

4 Q Mr. Baird, let me direct your attention to the conclusion
13:05:41 5 that the authors of this paper reached. And can you read
6 that, please.

7 A "The Bard Recovery and Bard G2 filters had high
8 prevalences of fracture and embolization, with potentially
9 life-threatening sequelae."

13:05:56 10 Q And fracture means that a portion of the filter broke
11 apart; correct? Is that your understanding?

12 A There's technical terms for fracture, but that could be
13 one of the definitions.

14 Q Do you understand that embolization means that whatever
13:06:08 15 fractured moved?

16 A Could move; correct.

17 Q And what these authors are concluding is that could be
18 potentially life-threatening to people; right?

19 A Correct.

13:06:17 20 Q And is this what Bard was reacting to when we talked about
21 earlier?

22 A One of many things.

23 Q And in terms of this article, did Bard consider, to your
24 knowledge, recalling the G2 line of filters at that point
13:06:30 25 based on the study?

DIRECT EXAMINATION (CONT'D) - BRET BAIRD

13:06:32 1 A Not that I know of, to my knowledge.

2 Q Did Bard consider issuing a warning letter to physicians
3 to make sure they had this information out there that
4 Dr. Nicholson --

13:06:40 5 A At that point I don't know. That's not my area of
6 expertise.

7 Q You're not aware of that happening?

8 A I'm not aware of it.

9 Q Now, as someone with a background in marketing, would you
13:06:51 10 agree that a product recall can hurt a brand's reputation?

11 A Sure.

12 Q And if a brand's reputation is hurt, that could hurt
13 market share; right?

14 A Sure.

13:07:03 15 Q Could lead to a loss of confidence for the customer?

16 A At that point I couldn't conjecture for the customer.

17 Q Certainly could create an opportunity for competition to
18 come in?

19 A Again, conjecture at that point, but, yes.

13:07:18 20 Q You think it's speculative that if reputation is hurting,
21 that customers might go to a different competitor?

22 A I agree.

23 Q You agree it's speculative? Or you agree that it could
24 happen?

13:07:29 25 A I agree it could happen. It's all conditional.

CROSS-EXAMINATION - BRET BAIRD

13:07:31 1 Q Now, certainly having an entryway for competition would
2 not a good thing for a company that is trying to hang on to
3 its narrow lead as the market leader in the IVC filter market;
4 right?

13:07:40 5 A Correct.

6 MR. CLARK: That's all the questions I have.

7 THE COURT: Cross-examination?

8 MS. HELM: Yes, Your Honor.

9 C R O S S - E X A M I N A T I O N

13:07:53 10 BY MS. HELM:

11 Q Good afternoon, Mr. Baird.

12 A Good afternoon.

13 Q You were asked in the beginning of your testimony if you
14 were being paid or had had discussions about being paid for
15 your time to be here today. Do you recall that?

16 A Yes.

17 Q Are you missing work today?

18 A I am.

19 Q Are you missing the opportunity to do what you get paid to
13:08:18 20 do today?

21 A Absolutely.

22 Q Are you seeking any compensation other than being
23 reimbursed for the time and money that you're missing by not
24 being able to be at work today?

13:08:27 25 A No.

CROSS-EXAMINATION - BRET BAIRD

13:08:32 1 Q You've been asked about a lot of documents that were
2 written a long time ago. And you left Bard in 2011; is that
3 right?

4 A Correct.

13:08:40 5 Q Have you done your best today to try to remember events
6 that occurred more than ten years ago?

7 A Yes.

8 Q One of the documents, one set of documents you were asked
9 about were documents called Franchise Reviews. Do you recall
13:08:55 10 those?

11 A Yes.

12 Q What is a Franchise Review? What was the purpose of that
13 when you were at Bard?

14 A Sure. It's a very typical activity, I guess is the best
13:09:05 15 way to say it, and that happens every six months. It's
16 something company wide. It's a very typical thing that one
17 does. In fact, it's a planning event that you do. Look for
18 opportunities to, as stated before, what's called three-year
19 budgeting. What projects you want to do, what improvements
13:09:26 20 you can do, how do you proceed forward as a company.

21 Q And did Bard require of that of every product line?

22 A Absolutely.

23 Q And so it was not unique to filters?

24 A Not at all.

13:09:36 25 Q And this concept of looking at your products and planning

CROSS-EXAMINATION - BRET BAIRD

13:09:39 1 ahead, based on your experience, is that unique to Bard?

2 A No. No. I've worked in other medical device companies,
3 and Medtronic was the one right before. They're constantly
4 innovating, constantly looking for new opportunities.

13:09:53 5 Q You were ask about a SWOT analysis. Do you recall that?

6 A Yes.

7 Q Is a SWOT analysis unique to Bard?

8 A Not at all.

9 Q Is a SWOT analysis a system to use to evaluate products,
13:10:08 10 processes, companies, any number of things?

11 A Yes. SWOT is primarily a marketing tool. It's something
12 provided as a standard marketing tool.

13 Q And with that SWOT analysis that you were asked about
14 previously, was that done in reaction to an issue with the
13:10:25 15 Eclipse filter?

16 A No.

17 Q Was that something, again, done as part of the company's
18 continuous improvement, continuous attempt to improve their
19 products and their marketing?

13:10:35 20 A Yes.

21 Q You were asked earlier or read a document that said the
22 purpose of marketing is to improve the reputation of the
23 product. Do you recall that?

24 A Yes.

13:10:48 25 Q Is that unique to Bard?

CROSS-EXAMINATION - BRET BAIRD

13:10:50 1 A To improve the reputation? No.

2 Q For marketing to have a purpose to improve the reputation

3 of the product.

4 A No. That's the role of marketing.

13:10:58 5 Q In any company anywhere?

6 A Any company anywhere, any industry.

7 Q That's what marketing's supposed to do; right?

8 A That's what we're supposed to do.

9 Q You were also asked a number of questions about changes to

13:11:12 10 the G2 for the Eclipse and then subsequent filters. Do you

11 recall that?

12 A Yes.

13 Q Okay. Before a product can go to market, before a filter

14 could go to market, what has to happen? Just generally what's

13:11:25 15 the big picture of what has to happen?

16 A It's very complex. Complex procedure. Typically you

17 start with an idea. We talked about idea POAs. The team

18 comes together and they discuss all sorts of things -- it's a

19 very complex system. So once you've identified an

13:11:42 20 opportunity, R&D works on it. There's potentially years of

21 testing. There's innovations that you can try to implement

22 onto the product or innovate, as we talked about, a brand-new

23 product, but there's a whole slew of activities. And once you

24 do that, you even have other team members who are involved in

13:12:00 25 it.

CROSS-EXAMINATION - BRET BAIRD

13:12:00 1 Q And in the progression of the filters at Bard from the G2X
2 or G2 Express to the Eclipse and then subsequent filters, did
3 the team make the decision to go ahead and make the changes
4 from the G2X to the Eclipse rather than waiting the years and
13:12:17 5 years of development of the other concepts that were in
6 process?

7 A Yes. That was a continual process of improvement.

8 Q Does the fact that Bard was continuing to look to ways to
9 improve its filters mean that there was a problem with the
13:12:29 10 existing filter?

11 A No.

12 Q Have you been involved in other companies that were --
13 that followed this concept of continuous improvement?

14 A Absolutely.

13:12:39 15 Q Do you think that that is what a prudent medical device
16 company should do?

17 A Yes.

18 Q Is that what Bard was doing?

19 A Yes.

13:12:46 20 Q You were asked a few questions about and the jury just
21 heard about the Nicholson article. Do you recall that?

22 A Yes.

23 Q Are you aware that Dr. Nicholson subsequently published a
24 correction to that article, that it actually had some errors
13:13:03 25 in it?

CROSS-EXAMINATION - BRET BAIRD

13:13:04 1 A Yes.

2 Q In the 2009-2010 time period, you mentioned there were a
3 lot of external forces going on in the IVC filter market. Do
4 you recall that?

13:13:18 5 A Yes.

6 Q And you were specifically asked about a document that
7 referred to breaking with the baggage of the G2 and the G2X.
8 Do you recall that?

9 A Yes.

13:13:28 10 Q What was that baggage?

11 A Well, there's a lot going on in the market. We had
12 filterlaw.com that was attacking our business, we had other
13 external forces. We had sales reps who were fabricating
14 things to try to attack our business. So there's all sorts of
15 things going on.

16 Q And from a marketing perspective and as the franchise
17 manager, was it your responsibility, from a marketing
18 perspective, to address those external forces, the
19 filterlaw.com, the competitors making up information?

13:13:56 20 A Absolutely. Our team's and then the marketing role is to
21 communicate those.

22 Q And did that end up taking a good portion of your time?

23 A Quite a bit of my time. Yes.

24 Q Did Bard take some action in response to filterlaw.com and
13:14:10 25 the information that the competitors were providing to

CROSS-EXAMINATION - BRET BAIRD

doctors?

A Yes.

Q What action did Bard take?

A I believe provided a letter to the customer.

MS. HELM: Can I pull up 8548, please.

MR. CLARK: Your Honor, may we approach?

THE COURT: Pardon?

MR. CLARK: May we approach?

THE COURT: We're going to put a limit on bench conferences.

We'll be right with you, ladies and gentlemen. Go ahead and stand up if you want.

(Bench conference as follows:)

MR. CLARK: Your Honor, this talks about legal websites, plural. Television advertisements. We been very clear and you've instructed the jury that we're just talking about the filterlaw website, so this is expanding dramatically what we'd be talking about.

And I think, as a factual matter, the filterlaw website did not go online until August 2009 so it's not even related to filterlaw.

THE COURT: Therefore what?

MR. CLARK: Therefore, the only door we've opened was the response to the baggage memo. We talked about filterlaw. The baggage memo is six or seven months from this date, so it

CROSS-EXAMINATION - BRET BAIRD

13:15:27 1 was fair game to talk about filterlaw, that was already
2 online, and that is what your ruling has been.

3 THE COURT: What do you mean six or seven from this
4 date --

13:15:36 5 MS. HELM: Filterlaw.com was --

6 THE COURT: Hold on.

7 MS. HELM: Sorry.

8 MR. CLARK: My concern --

9 THE COURT: What do you mean six or seven months from
13:15:40 10 this date? Before or after?

11 MR. CLARK: After. I'm sorry.

12 My understanding is August 2009 is when filterlaw.com
13 was launched. The baggage memo is April 2010. So this
14 precedes the baggage memo and also invites much broader use of
13:15:59 15 lawyer advertising which, again, is not what we agreed to and
16 not the door opened.

17 THE COURT: So you're suggesting I should not admit
18 it for that reason?

19 MR. CLARK: Correct.

13:16:07 20 MS. HELM: Your Honor, I don't have the date on
21 filterlaw.com. I asked the witness about this and he said
22 this was the reaction that the company -- if it predates
23 filterlaw.com, I stand corrected. I can't answer that
24 question.

13:16:20 25 THE COURT: Well, do you agree that the baggage memo

CROSS-EXAMINATION - BRET BAIRD

13:16:22 1 is ten months after this?

2 MS. HELM: Yes.

3 THE COURT: So how is this relevant to the baggage --

4 MS. HELM: Well, because the baggage memo refer- --
13:16:33 5 baggage refers back in time. The baggage is what occurred
6 prior to the date of that memo, and so these are events that
7 occurred prior to the date of the memo.

8 THE COURT: What is the relevancy of this document,
9 in your view?

13:16:44 10 MS. HELM: It goes to the fact that if -- he's talked
11 about marketing, and it goes to the fact of what marketing was
12 doing, what they were having to do. There's a number of
13 implications that there were problems with the G2 filter and
14 problems with the Eclipse filter that marketing was reacting
15 to when, in fact, they were reacting to these external forces,
16 these websites, and other things.

17 MR. CLARK: Your Honor --

18 THE COURT: Hold on.

19 MR. CLARK: Fine.

13:17:40 20 THE COURT: My concern, Ms. Helm, is that this memo
21 is about nothing other than lawyer lawsuits and advertisement.
22 That's the only topic addressed.

23 MS. HELM: Yes, sir.

24 THE COURT: And it says there are no class action
13:17:53 25 lawsuits against Bard. It does get directly into the whole

CROSS-EXAMINATION - BRET BAIRD

13:18:03 1 question of activities of plaintiffs' lawyers.

2 It seems to me --

3 MS. HELM: Your Honor, I'll move on.

4 THE COURT: Okay.

13:18:17 5 (Bench conference concludes.)

6 THE COURT: Thank you, ladies and gentlemen.

7 BY MS. HELM:

8 Q Mr. Baird, during the course of your work in the medical
9 device industry, have you had the opportunity to communicate
13:18:46 10 with physicians on occasion?

11 A On occasion, yes.

12 Q Are you -- and as a result of your work in the medical
13 device community, are you familiar with the information that's
14 available to physicians to evaluate a product such as an IVC
13:18:58 15 filter?

16 A Sure.

17 Q What information is available to them?

18 A There's a myriad of sources of information, one of which
19 would be, of course, their own peer to peer. So that is in
13:19:10 20 journals. There's others -- when I say peer to peer, doctors
21 to doctors.

22 National conferences where they present to each
23 other. Also, they've got access to information through
24 instructions for use, we call them IFUs, and there's data and
13:19:26 25 information in there. There's their own personal training as

REDIRECT EXAMINATION - BRET BAIRD

13:19:31 1 physicians. And -- that's all that comes to my mind right
2 now.

3 Q Medical literature?

4 A Medical literature, absolutely.

13:19:36 5 Q Based on your experience, marketing is a very small part
6 of the information that goes to doctors on an IVC filter. Do
7 you agree with that?

8 A Correct.

9 Q And despite the fact that you're a marketing person, would
13:19:49 10 you agree that from a physician's perspective, it's probably
11 the lowest part that they consider?

12 A Yes.

13 MS. HELM: Thank you. No further questions.

14 THE COURT: Any redirect?

13:20:02 15 MR. CLARK: Yes, Your Honor. Briefly.

R E D I R E C T E X A M I N A T I O N

16
17 BY MR. CLARK:

18 Q Mr. Baird, when we talked about the SWOT analysis, there
19 was no mention of filterlaw website in that analysis; correct?

13:20:18 20 A Correct.

21 Q Are you familiar with the G2 Platinum POA?

22 A Vaguely. It's an earlier name for -- I believe for -- for
23 Eclipse.

24 MR. CLARK: Could you please pull up Exhibit 592, I
13:20:40 25 believe. No, I'm sorry, 1742.

REDIRECT EXAMINATION - BRET BAIRD

13:20:43 1 BY MR. CLARK:

2 Q And, sir, this is a May 5, 2009, document.

3 A Correct.

4 Q And you're the preparer of this document?

13:21:02 5 A Correct.

6 MR. CLARK: Your Honor, I would move for admission of
7 this document in evidence.

8 MS. HELM: No objection, Your Honor.

9 THE COURT: Admitted.

13:21:12 10 (Exhibit 1742 admitted.)

11 MR. CLARK: May I publish, Your Honor?

12 THE COURT: Yes.

13 BY MR. CLARK:

14 Q And I think you told us that this was the project that
13:21:20 15 would become the Denali; is that right? Or the Meridian?

16 A G2 Platinum. I think that is Eclipse.

17 Q And here, they were going to -- if you look at page 2.

18 The idea was to create an electropolished filter, which is the
19 Eclipse; right?

13:21:45 20 A Which is the Eclipse, correct.

21 Q And in this document, if we go to the next page, at the
22 bottom there, we see Voice of Customer Plan.

23 Do you see that?

24 A Yes.

13:21:56 25 Q And it says: "User input was obtained for this project

REDIRECT EXAMINATION - BRET BAIRD

13:21:59 1 using a variety of means, including filter placement,
2 procedural observations, primary qualitative research, BPV
3 sales team input, BPV complaint history, MAUDE and FDA website
4 searches, Bard and IMS sales, clinical literature and
13:22:17 5 textbooks."

6 Did I read that correctly?

7 A Yes.

8 Q That's that sort of multi-disciplinary approach that you
9 talked about in terms of formulating these POAs?

13:22:26 10 A Correct.

11 Q And it doesn't say anything anywhere in Exhibit 1742 about
12 the filterlaw website; correct?

13 A Correct.

14 Q Sir, you, in your current line of work, work with trial
13:22:47 15 lawyers; right?

16 A Yes.

17 Q And you work with physicians who work with them, and you
18 coordinate reimbursement from lawsuits; right?

19 A Correct.

13:22:57 20 Q And, in fact, in your -- you have yourself created ads to
21 advertise for that type of work; right?

22 A Detail that.

23 Q Do you remember creating an ad where you were advertising
24 for the Arizona Trial Lawyers Association --

13:23:14 25 A Oh. Correct.

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13:23:15 1 Q -- years ago?

2 A Yes.

3 Q And that was to develop business from trial lawyers.

4 A Correct.

13:23:20 5 Q In this community.

6 A Correct. In Arizona.

7 Q And did you think there was something wrong with that at
8 the time?

9 A No.

13:23:28 10 Q And one of the things that you, as the franchise manager
11 at Bard, did was to create a response website to the
12 filterlaw.com called filterfacts.com; correct?

13 A Correct.

14 MR. CLARK: That's all the questions I have. Thank
13:23:47 15 you.

16 THE COURT: All right. Thanks, Mr. Baird. You can
17 step down.

18 MR. CLARK: For the next witness we call Guillermo
19 Bill Altonaga.

13:24:21 20 May I be permitted to read the background summary for
21 this witness?

22 THE COURT: This is going to be a video?

23 MR. CLARK: Video deposition.

24 THE COURT: You may.

13:24:30 25 MR. CLARK: Guillermo Bill Altonaga practiced as an

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13:24:34 1 optometrist for 19 years, after which he began work for a
2 medical device company in its field assurance department. In
3 2008 he began to work with Bard Peripheral Vascular as a
4 consultant, and then in 2010, became full-time employee of BPV
13:24:48 5 working in quality assurance and medical affairs where his
6 responsibility included providing clinical input into failure
7 modes analyses, health hazard evaluation, and promotional
8 materials. He is not a licensed medical doctor.

9 And, Your Honor, I would add there are no exhibits to
13:25:07 10 this deposition.

11 THE COURT: Okay.

12 (Video testimony of Guillermo Bill Altonaga was played.)

13 MR. CLARK: Your Honor, at this time the plaintiff
14 would call Dr. David Ciavarella, who will be presented via
13:43:25 15 video deposition.

16 I have some exhibits to move into evidence first.

17 The plaintiff would move into evidence trial
18 Exhibits 1216, 925, 991, 927, 931, and 1221.

19 MS. HELM: Your Honor, we have no objection to the
13:43:54 20 admission of those exhibits, but some are subject to the
21 Court's prior order and we'd just have to make sure they're
22 properly addressed.

23 THE COURT: Meaning redactions?

24 MS. HELM: Yes, Your Honor.

13:44:06 25 THE COURT: All right. Those exhibits are admitted

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13:44:08 1 subject to redaction by the parties.

2 (Exhibits 1216, 925, 991, 927, 931, and 1221 admitted.)

3 MR. CLARK: And, Your Honor, we have prepared a cheat
4 sheet to translate the trial exhibit number to the deposition
13:44:17 5 exhibit number. Would you like me to --

6 THE COURT: Have you shown that to defense counsel?

7 Any objection to the jury receiving that, Ms. Helm?

8 MS. HELM: Your Honor, I'm seeing it for the first
9 time. I don't know if it's accurate, but no, it's fine.

13:44:34 10 THE COURT: So you're not objecting?

11 MS. HELM: I don't have a basis to agree to it or
12 object. I'm -- excuse me. I don't have a basis to agree or
13 object, so I won't.

14 THE COURT: You won't agree or object. Okay.

13:44:44 15 Since there's no objection, you can give them to
16 Traci and she'll distribute them to the jury.

17 MR. CLARK: Thank you. May I approach?

18 THE COURT: Yes.

19 MR. CLARK: When those are handed out, Your Honor,
13:45:10 20 may I be permitted to read the summary?

21 THE COURT: Yes.

22 MR. CLARK: Dr. Ciavarella obtained his medical
23 degree from UCLA, then completed an internship and residency
24 at Roosevelt Hospital in New York City, followed by a
13:45:34 25 fellowship in hematology at the University of Washington.

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13:45:36 1 Dr. Ciavarella joined C.R. Bard in 2004 as vice
2 president of corporate clinical affairs. In that role
3 Dr. Ciavarella originally had responsibilities over both
4 clinical affairs, which oversees clinical trials, and medical
13:45:50 5 affairs, which provides the medical component to the quality
6 system and informs risk analyses.

7 In 2008, Dr. Ciavarella's role in clinical affairs
8 grew to the point that medical affairs was transitioned to
9 another individual.

13:46:04 10 Since 2004, Dr. Ciavarella's work has included Bard's
11 IVC filters, including the Recovery and the G2 filters.

12 (Video testimony of Dr. Ciavarella played.)

13 MR. O'CONNOR: Your Honor, our next witness will be
14 Michael Randall. He is here live.

14:24:58 15 Would you like us to get started?

16 THE COURT: Yes, let's get him and get started.

17 THE COURTROOM DEPUTY: Mr. Randall, if you'll please
18 come forward. Sir, stand right here and raise your right
19 hand.

20 **MICHAEL RANDALL,**

21 called as a witness herein, after having been sworn or
22 affirmed, was examined and testified as follows:

23 THE COURTROOM DEPUTY: Could you spell your last name
24 for the record.

14:25:44 25 THE WITNESS: R-A-N-D-A-L-L.

DIRECT EXAMINATION - MICHAEL RANDALL

1 THE COURTROOM DEPUTY: Thank you, sir. Please come
2 have a seat.

3 MR. O'CONNOR: Your Honor, before we get started, I'd
4 like to offer for admission into evidence Exhibit 1222.

5 MR. ROGERS: No objection, Your Honor.

6 THE COURT: Admitted.

7 (Exhibit 1222 admitted.)

8 BY MR. O'CONNOR:

9 Q Good afternoon, Mr. Randall. Would you state your full
10 name, please.

11 A Michael Adam Randall.

12 Q Mr. Randall, do you work for Bard at this time?

13 A Yes, I do.

14 Q Here in Arizona?

15 A Yes.

16 Q Are you the director of research and development?

17 A Yes. I'm a director. One of them. There's many.

18 Q How long has that been your position?

19 A I think for about three to four years.

20 Q How long have you been at Bard?

21 A Going on 12 years.

22 Q And you have been involved in a number of -- in various
23 filter projects?

24 A Yes.

25 Q As a matter of fact, you were the lead for a while. And

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14:27:01 1 was it the Platinum G2 project?

2 A Initially, yes.

3 Q And you, in the research and development department, work
4 with engineers and other people throughout Bard; is that
14:27:13 5 correct?

6 A That's correct.

7 Q You work with an engineer named Andrzej Chanduszeko?

8 A Yes, I do.

9 Q And in 2008, you and Mr. Chanduszeko conducted a meeting,
14:27:24 10 you developed the agenda for a meeting about -- the objective
11 of the meeting was the EVEREST study and MAUDE data. Do you
12 recall that?

13 A Andrzej put together a deck for that meeting; correct.

14 MR. O'CONNOR: Can we, Gay, please put up
14:27:40 15 Exhibit 1222.

16 BY MR. O'CONNOR:

17 Q Showing you Exhibit 1222, is this the slide deck that was
18 used at the meeting?

19 A I believe so. I'm not sure if it's the final draft.

14:28:04 20 MR. O'CONNOR: If you scroll through a couple of
21 pages. It's missing a page up front.

22 Gay, if you could scroll one or two pages.

23 THE WITNESS: I believe this is a draft.

24 BY MR. O'CONNOR:

14:28:15 25 Q Let's talk about this document, Mr. Chanduszeko.

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1 First of all, you were at Bard during the EVEREST
2 study; correct?

3 A I believe the EVEREST study was still going on when I was
4 there; correct.

5 Q And the EVEREST study was -- you knew that the G2 was
6 cleared originally -- the G2 filter was cleared originally as
7 a permanent device; correct?

8 A Yes.

9 Q And eventually the G2, Bard sought clearance for it as a
10 retrievable device; correct?

11 A Correct.

12 Q And the purpose of the EVEREST study was to study the
13 safety of the retrievability of the G2 correct?

14 A I believe so.

15 MR. O'CONNOR: Oh, yeah. Let's publish this.

16 May I publish, Your Honor?

17 THE COURT: Yes.

18 MR. O'CONNOR: Thank you.

19 BY MR. O'CONNOR:

20 Q And the meeting that you and Mr. Chanduszko were setting
21 up involved both the findings of the EVEREST study as well as
22 the MAUDE data; correct?

23 A Yes. It was an analysis of that.

24 Q And during this time there was discussion about a new
25 filter platform, the G2 Platinum; is that right?

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14:29:29 1 A Yes. Platinum. G2 Platinum.

2 Q And, according to Exhibit 122, the objective of the G2
3 Platinum was "To improve the G2 platform to address current
4 complications without a clinical trial."

14:29:50 5 Did I read that correctly?

6 A Yes. For this project that was the objective. We had
7 other projects that would have a clinical.

8 Q This was the project that you were talking about, this is
9 the one that's the subject of this document, and this was a
14:30:05 10 project where the objective was to have a filter without a
11 clinical trial. True?

12 A Yes. For this project.

13 Q And the discussions were how to overcome or address
14 current complications of the existing line of filters, which
14:30:21 15 were the G2 and the G2 -- well, the G2 at that time. True?

16 And the G2X?

17 A That's what the objectives here says.

18 Q And just so you and I are clear and everybody's on the
19 same page, this meeting occurred around June of 2008. Does
14:30:45 20 that sound right?

21 A I believe it's 2008. I'm not sure what month it is,
22 though.

23 Q I can show you an e-mail from Andrzej Chanduszek when he
24 forwarded the slides that said June 9, 2008. Would you like
14:30:58 25 to see that?

DIRECT EXAMINATION - MICHAEL RANDALL

14:30:58 1 A No, I'll take your word that he sent it to me that day.

2 Q Thank you.

3 And discussion about how the G2 Platinum would be
4 improved include features including electropolishing; correct?

14:31:18 5 Do you see where I'm reading?

6 A Yes. Electropolishing is one of the features we wanted to
7 add.

8 Q And you were also looking at reducing tilt, penetration,
9 migration. True?

14:31:31 10 A Yes.

11 Q And that's what you were saying this product, at least the
12 plan was, what this product would deliver to your customers.
13 Fair?

14 A Yeah, that was the objective of the project.

14:31:44 15 Q And on the same page, page 3 that we're looking at, there
16 were also risks that were considered by the people at your
17 meeting, including you and Mr. Chanduszko, which included
18 "unable to make changes to the filter without a clinical
19 trial." Correct?

14:31:58 20 A Correct.

21 Q And there was also concerns about timeline challenges
22 based on changes; correct?

23 A Correct.

24 Q And at this time the G2 was on the market. True?

14:32:14 25 A Yes, G2 was on the market.

DIRECT EXAMINATION - MICHAEL RANDALL

14:32:17 1 Q And the G2 filter was the subject of the EVEREST trial;
2 correct?

3 A Correct.

4 MR. O'CONNOR: Gay, would you go to page 6.

14:32:28 5 BY MR. O'CONNOR:

6 Q Mr. Randall, we're looking at a diagram that talks
7 complications and failures that were found or discovered
8 during the G2 EVEREST trial.

9 Do you see that?

14:32:51 10 A Yes.

11 Q And what do you call this, a Venn diagram?

12 A Correct.

13 Q And all together that trial involved -- there were at
14 least 100 patients enrolled; correct?

14:33:03 15 A I believe so.

16 Q And it was -- actually, the total patients that were
17 followed up, according to this slide, were 83.

18 Do you see that?

19 A Yes, I do.

14:33:13 20 Q And the objective of the study was to look at
21 retrievability during a period of time which the mean period
22 was about 140 days. Does that sound right?

23 A I don't know the specifics on how that trial was designed.
24 When I was at Bard at this time, I had just got to the
14:33:32 25 company, so I didn't work on this project.

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14:33:36 1 Q But you understood when you were getting ready for this
2 meeting that the goal of that project was to look at the
3 retrievability of the G2 filter. Fair?

4 A We weren't looking at the retrievability of the G2 filter.
14:33:48 5 This meeting here, we were looking at scoping out the G2
6 Platinum filter.

7 Q And I apologize. My question was bad.

8 Did you have an understanding that the EVEREST study
9 had looked at the retrievability?

14:33:58 10 A Yes, I knew.

11 Q And what is set forth in this slide are results of
12 complications from the EVEREST study; correct?

13 A Correct.

14 THE COURT: We're going to break at this point,
14:34:09 15 Mr. O'Connor.

16 MR. O'CONNOR: Sure.

17 THE COURT: We'll break for 15 minutes, ladies and
18 gentlemen. We'll resume at ten minutes to the hour. Please
19 remember not to discuss the case, and we'll see you then.

14:34:17 20 (The jury exited the courtroom at 2:34.)

21 MR. CLARK: Your Honor, by way of housekeeping, in
22 the Booker trial you'll recall that there was a problem with
23 the tape for Janet Hudnall. That's a witness we plan to play
24 this afternoon. Would we be permitted, or the Court
14:34:55 25 permitted, to give an explanation that there is a little break

DIRECT EXAMINATION - MICHAEL RANDALL

14:34:59 1 in the audio?

2 THE COURT: A little what?

3 MS. HELM: There was -- in the Booker trial, when we
4 played the Janet Hudnall tape, which we intend to play this
14:35:11 5 afternoon, there is a part in the video where it drops out and
6 we gave you a heads-up on that last time and you were able to
7 tell the jury if it goes out for a moment, it's just the tape.
8 And we were wondering if we could have the same information
9 provided to them, just so that they're not wondering.

14:35:25 10 THE COURT: Any objection?

11 MR. NORTH: No.

12 THE COURT: Let's do that as part of the
13 introduction. Just explain that.

14 MS. HELM: Thank you, Your Honor.

14:35:30 15 (Recess was taken from 2:35 to 2:50. Proceedings resumed
16 in open court with the jury present.)

17 THE COURT: Please be seated.

18 You may proceed, Mr. O'Connor.

19 MR. O'CONNOR: Thank you, Your Honor.

14:52:23 20 BY MR. O'CONNOR:

21 Q Mr. Randall, thank you for returning.

22 For the jury's benefit, to read this Venn diagram,
23 what this slide shows are the complications that were
24 discovered during the course of the EVEREST study; correct?

14:52:41 25 A Yes.

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14:52:42 1 Q And the red circle signifies the total number of filter
2 failures that involved tilt in those study participants;
3 correct?

4 A Yes, the total amount of tilts. If you add up all of
14:52:59 5 those numbers inside the red circle, those were the total
6 number of tilts observed.

7 Q Okay. Thank you. And I think there are 15 tilts.

8 And then if you look at the light blue circle, that's
9 the total number of caudal migrations; correct?

14:53:16 10 A Yes.

11 Q Yes?

12 A Yes.

13 Q And then to the left there, the yellow circle are
14 penetrations.

14:53:29 15 A Correct.

16 Q Meaning legs penetrating through the vena cava wall;
17 correct?

18 A It could be legs or arms, and it's anything more than
19 3 millimeters outside the contrast column --

14:53:45 20 Q Thank you for the clarification. You were looking at the
21 study and had specific definitions, but, for the jury's
22 benefit, the point you're making is the G2 had a two-tiered
23 system with arms and then longer legs?

24 A Correct.

14:53:58 25 Q And that's how it would seat itself inside the vena cava.

DIRECT EXAMINATION - MICHAEL RANDALL

14:54:01 1 True?

2 A Yes. Correct.

3 Q And those legs and arms would be involved in the
4 clot-catching function of the filter?

14:54:09 5 A Yes.

6 Q And when we look at these circles in the Venn diagram,
7 there's overlap. True?

8 A Correct.

9 Q And what the overlap shows are the different events where
14:54:28 10 there were more than one complication; correct?

11 A Correct.

12 Q For example, the 2 that's between the red and yellow, do
13 you see where I'm talking about?

14 A Yes.

14:54:43 15 Q That means there was a complication that involved both
16 tilt and penetration. Right?

17 A That's correct.

18 Q And then just below that with the intersection of the
19 blue, yellow, and orange, with the 3 with the asterisk, that
14:55:00 20 means there were three that had tilt, penetration, and caudal
21 migration; correct?

22 A That's correct.

23 Q And so for the jury's benefit, that's how the jury can
24 look at this when they view this, they can look at it and know
14:55:15 25 that there were total number of patients followed up, 83, and

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1 a specified period of time in a study that studied
2 retrievability, and the complications were recorded and the
3 Venn diagram shows the complications and also shows filters
4 that had more than one complication; correct?

5 A Correct.

6 Q Thank you.

7 So, for example, looks like there were a total of 18
8 penetrations. Some of those overlapped with other failures.
9 Fair?

10 A Correct.

11 Q It looks as though there were 15 tilts and some of those
12 tilts overlapped with other complications; correct?

13 A Correct.

14 Q And there were caudal migrations. True?

15 A True.

16 Q How many?

17 A Ten, it looks like here.

18 Q Pardon me?

19 A Ten.

20 Q And those also -- there were, among those ten, filters
21 that suffered more than one complication; right?

22 A Correct.

23 Q And also during this, in the slide presentation that was
24 prepared --

25 MR. O'CONNOR: If you go to page 10, Gay.

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14:56:46 1 BY MR. O'CONNOR:

2 Q -- there was data collected from the MAUDE database; is
3 that correct?

4 A That is correct.

14:56:57 5 Q Regarding the G2 filter. True?

6 A Yes. I believe this is G2.

7 Q And for the benefit of the jury, MAUDE, M-A-U-D-E, stands
8 for Manufacturers and User Facility Device Experience
9 database; is that right?

14:57:16 10 A I believe so.

11 Q And that is where Bard has an obligation to report adverse
12 events to the FDA?

13 A Bard, hospitals, different facilities, yes.

14 Q You're not suggesting -- you understand that Bard has a
14:57:33 15 mandatory responsibility to report adverse events. You
16 understand that. True?

17 A Yes.

18 Q And when you look at this Venn diagram regarding filter
19 complications that were reported to MAUDE concerning the G2,
14:57:52 20 here again we can see that there are filters that had events
21 involving fractures, tilt, and caudal migration. True?

22 A True.

23 Q But then there were other filters who had one or more of
24 the complications in a patient; correct?

14:58:11 25 A Correct.

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14:58:12 1 Q So if the jury wants to know, they could look at this and
2 see that 31 patients in the data that were looked at had 31
3 filters that caudally migrated and tilted. True?

4 A True.

14:58:28 5 Q And that there were six that suffered from all three of
6 the failures; correct?

7 A Correct.

8 Q And then, of course, there were fractures that were
9 combined with tilts; correct?

14:58:48 10 A Correct.

11 Q Thank you.

12 Now, you do know that a deficiency of the MAUDE
13 database is underreporting. True? You've heard that?

14 A I've heard that statement before.

14:59:23 15 Q We just heard from Dr. David Ciavarella. Did you know
16 him?

17 A I know who Dr. Ciavarella is, yes.

18 Q Dr. Ciavarella just testified that it may be only 1 to 5
19 percent of actual adverse events are reported. Do you have
14:59:38 20 any reason to dispute that?

21 A I wouldn't have any idea.

22 MR. O'CONNOR: Go to Page 12, Gay.

23 BY MR. O'CONNOR:

24 Q And here in the slide presentation that Bard was showing
14:59:58 25 in its meeting, it was stated that "The greatest number of

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15:00:05 1 complications is associated with tilts and migrations followed
2 by penetrations."

3 Did I follow that -- did I say that correctly?

4 Excuse me.

15:00:16 5 A Yes, you did.

6 Q It says "This is contrary to the EVEREST data."

7 Do you see where I'm at?

8 A Yes.

9 Q "And one possible explanation is that some asymptomatic
15:00:27 10 penetrations are not reported."

11 Did I read that correctly?

12 A Yes, you did.

13 Q And that's something that you were aware of, that there
14 could be patients out there with Bard filters who were unaware
15:00:38 15 of the failures because they were not experiencing symptoms at
16 the time. You're aware of that, aren't you?

17 A Most filter complications are asymptomatic.

18 Q You're aware that with respect to Bard filters, staying
19 with Bard, there are patients out there that may have filter
15:00:56 20 complications who are unaware of those complications. True?

21 A Yes. In terms of what this says here, yes.

22 Q And a concern that was stated in this presentation is that
23 "MAUDE shows more fractures than EVEREST. One possible
24 explanation is that some tilts and caudal migrations are not
15:01:25 25 reported."

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15:01:25 1 Now, did I read that correctly?

2 A You read that correctly.

3 Q And, again, assuming that what Dr. Ciavarella said, that
4 it may only be 1 to 5 percent, that makes sense that not all
15:01:44 5 failure -- filter failures, Bard filter failures, are reported
6 to the MAUDE database; correct?

7 A I'm sorry, can you say that question again.

8 Q Sure. And assuming what Dr. Ciavarella testified to, this
9 is also suggesting that not all Bard filter complications are
15:02:00 10 reported to MAUDE data; correct?

11 A Correct.

12 Q Another issue that was addressed at this meeting is
13 penetrations. "Penetrations are associated with caudal
14 migrations and tilts."

15:02:16 15 Did I read that correctly?

16 A Yes, you did.

17 Q And that's something that we just saw in the Venn
18 diagrams; correct?

19 A Yes.

15:02:24 20 Q Relationship between one failure to another. True?

21 A Yes. Shows there was overlap.

22 Q In other words, what we saw was that there are filters
23 that just don't experience one failure, but experience more
24 than one failure; and the issue here was whether one failure
15:02:43 25 led to other failures; correct?

DIRECT EXAMINATION - MICHAEL RANDALL

15:02:49 1 A I don't understand that question. Can you repeat that?

2 Q Well, "Penetrations are associated with caudal migrations
3 and tilts."

4 Did I say that correctly?

15:02:57 5 A Yes. You did.

6 Q Meaning there was an issue and -- an issue that was being
7 discussed whether there was a relationship between
8 penetrations, caudal migrations, and tilts. In other words,
9 that one leads to another. You recall that being a concern;
15:03:17 10 correct?

11 A I don't know if it was a concern. We had a hypothesis
12 that we wanted to stop movement, and if we did that we think
13 we could address penetration, help reduce it, help reduce
14 caudal migration, help reduce tilt.

15:03:31 15 Q Whether it was a concern or hypothesis, it was stated in
16 June of 2008; correct?

17 A I believe in here there's a hypothesis that states that.

18 MR. O'CONNOR: Let's go to page 13.

19 BY MR. O'CONNOR:

15:03:53 20 Q And still staying with the G2, in June of 2008, according
21 to this Bard document, "Caudal migration, tilt, perforation,
22 and fractures are the most commonly occurring complications
23 associated with the filter."

24 Did I read that correctly?

15:04:14 25 A Yes, you did.

DIRECT EXAMINATION - MICHAEL RANDALL

15:04:15 1 Q And we saw that in the Venn diagrams. True?

2 A Yes.

3 Q It goes on to say that "Eliminating these failure modes
4 would reduce number of filter complaints from 152 to 34," or,
15:04:35 5 paren, "by 78 percent," close paren, period.

6 Did I read that correctly?

7 A Yes, you did.

8 Q Meaning that the concern or hypothesis was this: That if
9 Bard could eliminate failure modes that it would likely reduce
15:04:56 10 the number of filter complications; correct?

11 A Absolutely. We felt if we could eliminate these filter
12 failure modes here, which are the most common filter failure
13 modes, it would reduce complications. So that's what we were
14 striving to do.

15:05:19 15 MR. O'CONNOR: Go to page 16.

16 BY MR. O'CONNOR:

17 Q And in June 2008, preparing the statement, the people at
18 Bard said "It is believed that caudal migration leads to
19 tilts, perforations, and fractures."

15:05:37 20 Did I read that correctly?

21 A Yes, you did. I don't know if this is the final
22 hypothesis we put in since this is a draft document, though.

23 Q It was prepared by people at Bard. True?

24 A It was prepared by Andrzej.

15:05:52 25 Q Andrzej Chanduszeko. And he is an engineer that has been

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15:05:57 1 at Bard quite a while. True?

2 A Yeah. But I don't know if this was the final document.

3 Q This was prepared by Andrzej Chanduszek, that's all I'm
4 asking. Yes or no?

15:06:05 5 A Oh. Yes.

6 Q And what's his position, sir?

7 A Andrzej is a principal engineer right now.

8 Q And he's been at Bard quite a while, hasn't he?

9 A Yes.

15:06:15 10 Q And at Bard, the engineers do look at failure modes and
11 complications, don't they?

12 A Yes.

13 Q And the engineers do look at ways to design the filter to
14 prevent or minimize complications. True?

15:06:36 15 A Absolutely.

16 Q And the engineering department is separate from research
17 and development? Or are they all one?

18 A Well, there's different engineers. So there's engineers
19 in research and development, there's engineers in quality,
15:06:50 20 there's engineers in field assurance.

21 Q So the engineers in research and development are the
22 groundwork of looking at how can we make the filter safer and
23 prevent or reduce the complications we're seeing. Is that
24 fair?

15:07:06 25 A Yeah. The goal of the engineers in R&D is to enhance

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15:07:11 1 performance.

2 Q And you have that group in Tempe, Arizona; right?

3 A Correct.

4 Q But also in Tempe, Arizona, you have another group, you've
15:07:18 5 got marketing people; right?

6 A Yes, we do.

7 Q And their job is to assist the sales force in getting the
8 knowledge out there about the devices; correct?

9 A One of their roles, yes.

15:07:29 10 Q And you know the people in marketing, don't you?

11 A Yes, I know who works in marketing.

12 Q And you've worked with people in marketing and sales;
13 correct?

14 A Marketing for sure. Sales is an outside -- they're not in
15:07:43 15 the building. But I know some sales reps.

16 Q But you know the sales force at Bard are the persons, the
17 people, that interact with the doctors who are the customers
18 of Bard; correct?

19 A The sales reps do; correct.

15:07:57 20 Q And when it comes to Bard and its relationship with its
21 consumers, the doctors, the sales force are the linchpin;
22 right? They're the connector.

23 A They deal with the physicians.

24 Q Essentially the sales force is the face of Bard; correct?

15:08:15 25 For the physicians. Physicians have more interaction with

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1 sales force at Bard than any others.

2 A Yeah.

3 Q That makes sense to you; right?

4 A Yeah, they deal with the physicians.

5 Q And back in June 2008 --

6 MR. O'CONNOR: If we could go to 17, Gay.

7 BY MR. O'CONNOR:

8 Q -- Bard, through MAUDE data, other sources, including the
9 EVEREST study, knew that the G2 was experiencing failures,
10 including failures with caudal migration; correct?

11 A Yes. We knew about these failure modes.

12 Q And as a matter of fact, back in June of 2008 there were
13 discussions about design changes that could reduce or
14 eliminate those failure modes. Fair?

15 A You said back in -- I didn't hear the year.

16 Q I'm going back to 2008, when this meeting was happening.

17 A Um-hmm.

18 Q Yes?

19 A Yes.

20 Q And knowing that the G2 and its predecessor had failures
21 that included caudal migration, cephalad migration, tilts,
22 perforations, and fractures, in 2008 your group and the
23 engineers were looking at how to reduce that. Is that fair?

24 A You threw me off. You said cephalad migration. Were you
25 talking about EVEREST data when you said that?

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15:09:56 1 Q I'll take cephalad out of the question.

2 And to your point, EVEREST dealt with G2?

3 A Correct.

4 Q The issue with G2 was primarily down migration, caudal
15:10:06 5 migration; correct?

6 A I wouldn't say issue. There were reported complications
7 below 1 percent for those. But that was a known complication;
8 correct.

9 MR. O'CONNOR: Well, I move to strike because that's
15:10:16 10 nonresponsive.

11 THE COURT: Overruled.

12 MR. O'CONNOR: All right.

13 BY MR. O'CONNOR:

14 Q The point is, is that in 2008, engineering was looking at
15:10:26 15 ways to eliminate or reduce that complication. True?

16 A Yes, that was one of the goals.

17 Q And what you were looking at was how to reduce fractures
18 through electropolishing the surface and using a low inclusion
19 wire. True?

15:10:44 20 A True.

21 Q And you were looking at reducing tilt, penetration, and
22 migration, and you were looking at design changes to reduce
23 those complications; correct?

24 A Yes, that was the goal of that project.

15:11:00 25 Q And you were certainly familiar and knew about something

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15:11:05 1 that could be considered to reduce or eliminate caudal
2 migration, and that was caudal anchors; correct?

3 A At this particular time here, I'm not sure if we had that
4 solution yet.

15:11:20 5 Q You knew about the solution, though, didn't you?

6 A What do you mean do you know about the solution?

7 Q You were aware of the concept of caudal anchors back then.
8 True?

9 A Caudal anchors, yes, but in itself caudal anchors is
15:11:33 10 not -- you still have to design it for the part, which is very
11 challenging. So we didn't have a solution for caudal anchors.

12 Q My question's different.

13 A I'm sorry. Go ahead.

14 Q You knew there was a design feature that was around as
15:11:45 15 early as 2008 and earlier that was being used to address
16 caudal migration. Fair?

17 A Not for this design, no.

18 Q Well, there were caudal anchors that you were aware of;
19 correct?

15:12:00 20 A Caudal anchors keeping something to move down on a
21 permanent filter we were aware of. Not for a retrievable
22 filter.

23 MR. O'CONNOR: Go to page 26, please, Gay.

24 BY MR. O'CONNOR:

15:12:36 25 Q And this is risks in terms of discussing what to do about

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15:12:41 1 the complications. Is that a fair reading of this slide?

2 A I'm sorry, can you repeat your question.

3 Q Sure. In looking at this slide, Risks, the concern still
4 is what can be done to improve or reduce the complications
15:13:01 5 that this meeting was about. Is that a fair reading?

6 A No, that's not how I interpret this.

7 Q You talk about existing test methods.

8 See where I'm reading?

9 A Yes. What this is saying is that you have to be careful
15:13:17 10 when you design and implement a solution because that solution
11 that you implement can cause a negative effect. So, for
12 instance, we were talking about caudal anchors. If you put
13 caudal anchors on the filter, if you don't do it right you may
14 not get the right wall apposition and you might cause
15:13:39 15 migrations.

16 Q Just hang on, Mr. Randall. Let me just get this one
17 point.

18 The last sentence says "Existing test methods may not
19 be able to fully assess negative effects."

15:13:50 20 Did I read that correctly?

21 A Yes, you did.

22 Q And Bard had tests for various failure modes back when it
23 was developing the Recovery and G2; correct?

24 A Correct. But that last sentence is talking to if we made
15:14:08 25 a change, we may not be able to figure out the negative

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15:14:10 1 consequence of that change with the existing test method.

2 Q All I'm looking at is you had existing test methods and
3 your concern was whether they would be adequate at the time.
4 Is that fair reading?

15:14:23 5 A For the change. Correct.

6 Q For the change to the filter.

7 A Yes.

8 Q Meaning if you're going to change the filter, you might
9 have to change the test.

15:14:33 10 A We -- or may need a new test.

11 Q Certainly something that engineers are capable of doing;
12 correct?

13 A Correct.

14 Q Certainly something that -- Bard has an engineering force.

15:14:46 15 If they need a new test to develop a design feature in a
16 filter, they can and should do it if the filter is failing.
17 True?

18 A Yeah. I think you if you can make improvements, you
19 should definitely strive to make improvements.

15:15:02 20 Q I mean, if the existing tests are not accurately
21 predicting what's going on out there in the field or in the
22 real world, then a company like Bard should reexamine the
23 testing.

24 A That's not what this is saying. This is saying as we do
15:15:14 25 the project --

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15:15:15 1 Q My question is different, sir.

2 THE COURT: Please don't interrupt. Let him answer
3 the question.

4 THE WITNESS: I thought we were talking about -- in
15:15:21 5 this context here, what this is saying is if we made a change,
6 our current existing tests may not be sufficient to handle
7 this change because it was new technology that we're adding
8 and that new technology could lead to a different failure
9 mode. So it just said, hey, let's recognize that this is a
15:15:40 10 risk. Let's not overlook it. So that's what this whole
11 section is about, to make sure that the engineers did not
12 overlook the risk that you could do something thinking you're
13 making a good, positive solution, but it could be bad for the
14 product. So that's what this slide really represents.

15:15:56 15 BY MR. O'CONNOR:

16 Q All right. My question's a little bit different.

17 A Okay.

18 Q The purpose of testing at Bard, testing filters, is to
19 help engineers and the people at Bard have some predictability
15:16:09 20 of how filters may act when they're out there in the public;
21 correct?

22 A Correct. We have to test it and make sure we do it to the
23 best we can.

24 Q And if Bard finds that filters are failing more than
15:16:26 25 predicted by their tests, their bench tests and other tests,

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1 then Bard should look at changing the test. Do you agree with
2 that?

3 A I think within reason. It's kind of hard to connect those
4 to the bench testing.

5 Q But you should always examine, can something be done to
6 improve the testing to help us have better predicability of
7 what will happen once this device is out in the public. True?

8 A Yeah, we constantly try to improve.

9 Q Now, on this idea about caudal anchors --

10 MR. O'CONNOR: Gay, please go to Exhibit 591.

11 BY MR. O'CONNOR:

12 Q We just heard --

13 MR. O'CONNOR: Your Honor, I believe this is in
14 evidence. May I publish to the jury?

15 THE COURT: Yes.

16 BY MR. O'CONNOR:

17 Q This is Exhibit 591, Mr. Randall, and it's an Idea POA,
18 Product Opportunity Appraisal.

19 Do you see that?

20 A Yes, I do.

21 Q Have you seen these documents before?

22 A Yes.

23 Q And the date of this is August 2009; correct?

24 A Correct.

25 Q And, by the way, the Eclipse filter was cleared and

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1 released for market in January of 2010; right?

2 A I believe so.

3 Q And so this is before the release of the Eclipse filter
4 and during the period of the G2 and the G2X filter; right?

5 A I believe so.

6 Q And you were involved in the G2X. True?

7 A Yes.

8 Q And what you did was you took the G2 and you figured out
9 how to put a hook on top; correct?

10 A That was one of the changes.

11 Q A hook that would assist doctors in retrieving the filter;
12 correct?

13 A For snare retrievability a hook was added, and then there
14 were also some delivery system changes, hemostasis valves
15 added preventing blood loss and improving the product that
16 way.

17 Q You testified, though, the G2X was essentially the G2 with
18 a hook.

19 A It is -- there's a hook on it; correct.

20 Q And in August of 2009 there was an idea product
21 opportunity appraisal entitled Denali Idea POA.

22 Do you see where I'm reading?

23 A Yes.

24 MR. O'CONNOR: And if we go to page 2, Gay.

25 And, Gay, if you would, in the first paragraph,

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15:19:42 1 highlight "Bard is the market leader." It's the second
2 sentence.

3 Highlight the whole sentence, I'm sorry.

4 BY MR. O'CONNOR:

15:20:18 5 Q In August of 2009 in the Bard product opportunity
6 appraisal, Mr. Baird wrote that "Bard is the market leader for
7 sales of optional filters in the United States but only by a
8 slim margin."

9 Did I read that correctly?

15:20:31 10 A Yes, you did.

11 Q And the way Bard was using the term "optional filters,"
12 those were filters that were permanent that also had the
13 option to be retrieved. True?

14 A That's correct.

15:20:43 15 Q So, in other words, originally when it first came to the
16 market, the G2, as you know, was cleared to be a permanent
17 filter only; right?

18 A Yes, that's what I remember.

19 Q And it was sometime later where it went and received a
15:20:57 20 clearance to also have retrievability; correct?

21 A Correct.

22 Q But it was always promoted as a permanent filter that had
23 the option of being retrieved. True?

24 A I don't know how it was promoted, but it's an optional
15:21:12 25 filter. The sales guys promote the product for marketing.

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15:21:16 1 Q All right. But you understand that the G2 was always a
2 permanent filter and had the option to be retrieved; correct?

3 A Correct. That's what option means.

4 Q You knew from Bard's history that Bard had a permanent
15:21:28 5 filter known as the Simon Nitinol filter; correct?

6 A Yes.

7 Q And permanent filter means a filter that is intended to
8 stay in a patient's body, in her vena cava, for the entirety
9 of his or her lifetime. True?

15:21:42 10 A Permanent. Nonretrievable. Correct.

11 Q Mr. Baird went on to write: Offering a new device with
12 improved resistance to movement, fracture, and penetration
13 while maintaining long-term retrievability will help
14 strengthen our position and capture more share.

15:22:09 15 Did I read that correctly?

16 A Yes, you did.

17 Q And that was something you were aware of during the entire
18 time you've been at Bard all the way through now, the present
19 time, is that the filter market, like any medical device
15:22:24 20 market, is a competitive market; correct?

21 A It's a competitive market, correct, and --

22 Q And Bard -- Bard, according to this document, wanted to
23 make sure -- wanted to take steps to capture its market share.
24 Fair?

15:22:39 25 A Well, wanted to improve the product too.

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15:22:41 1 Q Improve the product --

2 A Wanted to be the leader in filters, so in order to be the
3 leader you've always got to be striving to be the best.

4 Q Right. And so in the next paragraph we can see that in
15:22:53 5 trying to figure out how to capture market share, there was a
6 discussion about inputs from customers.

7 MR. O'CONNOR: Can you put the first sentence in,
8 Gay, of the second paragraph.

9 BY MR. O'CONNOR:

15:23:25 10 Q Mr. Baird wrote that some of the most common inputs we
11 receive from customers and the sales force -- customers are
12 likely doctors, is that correct, Mr. Randall?

13 A Yes, I would say so.

14 Q And the sales force, they're out there every day talking
15:23:41 15 to doctors; right?

16 A They deal with the physicians.

17 Q "Some of the most common inputs we receive from customers
18 and the sales force for the G2 and G2X products pertain to
19 filter complications that compromise retrievability, including
15:23:57 20 filter migration, tilt, and penetration."

21 Now, did I read that correctly?

22 A Yes, you did.

23 Q And, as a matter of fact, when we just went through the
24 slide presentation that was part of the meeting that you wrote
15:24:10 25 the agenda for in June 2008, we saw the Venn diagrams that

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15:24:16 1 talked about those fractures -- those failure modes; correct?

2 A Yeah. Those are --

3 Q Migration, tilt, and penetration. Fair?

4 A Yes. Those are the failure modes for all filters.

15:24:29 5 Q Well, here, this document's talking about the G2 and G2X;
6 correct?

7 A Yes, this is input from the sales force on G2 and G2X.

8 Q And Mr. Baird wrote on behalf of Bard, "In order to reduce
9 these types of complications, this project will incorporate
10 design modifications that will help limit the movement, keep
11 the filter centered, and minimize fracturing."

12 Did I read that correctly?

13 A Yes, you did.

14 Q And back in September of 2009, the modifications to limit
15 movement, keep the filter centered, and minimize fracturing
16 included the following: Penetration limiters.

17 A Um-hmm.

18 Q A feature that would minimize the filter legs and arms
19 from penetrating through the vena cava wall; correct?

15:25:26 20 A Yeah.

21 Q That's what a penetration limiter is.

22 A Yeah. Trying to dissipate the radial strength, that's
23 what we were trying to do.

24 Q Caudal anchors.

15:25:35 25 A Yes.

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15:25:36 1 Q A design feature that will prevent the filter from moving
2 downward. True?

3 A Correct.

4 Q Talking about Denali, a laser cut one-piece design.

15:25:48 5 Do you see that?

6 A Yes, I do.

7 Q An electropolished finish.

8 A Um-hmm.

9 Q Enhanced design with broad shoulders for centering.

15:26:02 10 Did I read that correctly?

11 A Yes, you did.

12 Q Now, in January of 2010, Bard released the Eclipse filter;
13 correct?

14 A I believe it was in January. Well, 2010, for sure. Not
15 sure what month.

16 Q Well, assuming that there are documents that said it was
17 released in early 2010, does that make sense to you?

18 A Yeah.

19 Q And you agree that the design changes in the Eclipse did
15:26:51 20 not address penetration.

21 A For Eclipse. The enhancements did not address those.

22 Q So that you and I are on the same page, you agree design
23 changes in the Eclipse did not address penetration. True?

24 A It -- those design enhancements were not focused on
15:27:12 25 penetration, that is correct.

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15:27:14 1 Q All right. The design changes in the Eclipse did not
2 address tilt; correct?

3 A Correct.

4 Q The design changes in the Eclipse did not address
15:27:26 5 migration. True?

6 A True. There were no enhancements for that.

7 Q In fact, the Eclipse was an electropolished version of the
8 G2; correct?

9 A It was -- we took the G2X and electropolished those
15:27:47 10 components.

11 Q So you took the G2 with the hook you designed for the G2X,
12 electropolished the legs, and essentially you had the G2X with
13 electropolished legs; correct?

14 A Legs, arms, and the snare tip.

15:28:04 15 Q And that's how you released the device in 2010?

16 A 2010 was electropolishing.

17 Q I can show you in your deposition, if you like, where you
18 testified about the launch in January 2010. Do you agree with
19 me or do you want me to show you your deposition?

15:28:39 20 A No, it's in there. I just don't remember all those dates
21 off the top of my head.

22 Q Here's what else you testified to: Safety and
23 effectiveness are the most important job of a medical device
24 company.

15:28:50 25 You agree with that. True?

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15:28:52 1 A Safety and effectiveness are definitely important, yeah,
2 for medical device companies.

3 Q Just let me wrap it up here, Mr. Randall. I appreciate
4 your time today.

15:29:25 5 So if we look at that meeting that occurred at Bard
6 back in June of 2008 and then we fast-forward to January of
7 2010, year and a half, that meeting addressed -- in 2008
8 addressed the failures that were seen in studies and in the
9 MAUDE database that involved the G2; correct? We just talked
10 about that.

11 A You're talking about the PowerPoint for the G2 Platinum?

12 Q Yes.

13 A Yes.

14 Q Then in January of 2010, the Eclipse was released and --
15 true?

16 A Yeah. True.

17 Q And in 2010, a year and a half after that 2008 meeting,
18 Bard released a filter that did not have design changes to
19 address tilt, caudal migration, or perforation; correct?

15:30:33 20 A Correct. There were other filter projects still going
21 along at the same time.

22 Q Filter that was released, that Eclipse, did not address
23 those failure modes; correct?

24 A It had no enhancements for those.

15:30:54 25 Q And just so you and I are clear, again, the EVEREST study

CROSS-EXAMINATION - MICHAEL RANDALL

1 was a relatively short-term study; it was not a long-term
2 study; correct? You understood it was just about six months,
3 true, to look at retrievability?

4 A I don't remember the contents or the details on EVEREST.
15:31:22 5 I wasn't a part of that. But I know that data is summarized
6 somewhere.

7 Q But it was a study for retrievability; right?

8 A I do know that.

9 Q And it didn't involve the Eclipse, it was the G2.

15:31:33 10 A Yes, G2 filter.

11 MR. O'CONNOR: That's all I have.

12 THE COURT: Cross-examination?

13 MR. ROGERS: Yes, Your Honor. Very briefly.

14 C R O S S - E X A M I N A T I O N

15:31:43 15 BY MR. ROGERS:

16 Q Good afternoon, Mr. Randall.

17 A Afternoon.

18 MR. ROGERS: Could we get Exhibit 1222 back up, the
19 PowerPoint, please.

15:32:01 20 And would you go to page 6, please.

21 BY MR. ROGERS:

22 Q All right. Mr. Randall, do you have that on your screen?

23 A Yes, I do.

24 Q Do you recall being asked questions about this particular
15:32:16 25 document by plaintiff's counsel?

CROSS-EXAMINATION - MICHAEL RANDALL

15:32:17 1 A Yes.

2 Q And I believe this is clear, but this particular document,
3 does it relate to the EVEREST study?

4 A Yes. This is gathered from that data.

15:32:29 5 Q And that was a clinical study that was done by Bard?

6 A Correct.

7 Q And if you look at the intersecting circles, were you
8 asked about those by plaintiff's counsel?

9 A Yes.

15:32:40 10 Q I don't recollect if you were asked about the one circle
11 that is to the left, the green circle about fractures. Were
12 you asked about that?

13 A No.

14 Q And can you explain for the jury what that means, the
15 green circle, please?

16 THE COURT: Counsel, do you want this displayed?

17 MR. ROGERS: Yes, Your Honor. I apologize. Yes,
18 would you please publish it. Thank you.

19 THE COURT: Yes.

15:33:02 20 BY MR. ROGERS:

21 Q Let me ask you again, Mr. Randall. You were asked about
22 the intersecting circles --

23 A Correct.

24 Q -- correct?

15:33:10 25 And the one circle that is to the left, the green

REDIRECT EXAMINATION - MICHAEL RANDALL

15:33:14 1 circle, you were not asked about.

2 A No. No.

3 Q And can you explain for the jury what that circle
4 represents.

15:33:22 5 A Yeah. That was there was one fracture in the EVEREST
6 study. And the asterisk kind of shows it there. So we
7 couldn't really put that in the Venn diagram. So it was just
8 one fracture.

9 Q And does that one fracture, did it have any of those other
15:33:43 10 failure modalities in that filter?

11 A Yeah. It had -- it's in the middle with the 3, so
12 penetration, caudal migration, tilt.

13 Q Okay. Thank you, Mr. Randall.

14 MR. ROGERS: I don't have any further questions,
15:34:00 15 Your Honor.

16 THE COURT: Any redirect?

17 MR. O'CONNOR: Just quickly.

18 Go ahead and put that back up, please.

R E D I R E C T E X A M I N A T I O N

15:34:10 20 BY MR. O'CONNOR:

21 Q You understood that the EVEREST study was a limited period
22 of time, correct, with a patient sampling of 83?

23 A 100 patients. There was patients lost to follow-up, so
24 looks like 83 they got data on.

15:34:40 25 Q So if this study lasted, let's say, 140 days, this would

REDIRECT EXAMINATION - MICHAEL RANDALL

1 be the collection of fractures seen within that period of
2 time; correct? Whatever period the study took, this is a
3 recording of what failures were discovered during that period
4 of time.

15:34:55 5 A Yeah. For that time span.

6 Q But then if you go and you look at -- just one moment.
7 I'm looking for the MAUDE data. Excuse me.

8 MR. O'CONNOR: Go to page 10, Gay.

9 BY MR. O'CONNOR:

15:35:30 10 Q In this collection of events from the MAUDE database,
11 there's significantly more failures including fractures, you
12 agree with that, than what we just saw in the EVEREST study?

13 A Yeah. There's more filters being sampled here too.

14 Q Right.

15:35:53 15 And as we said before, there are also patients out
16 there that may have Bard filters who are asymptomatic and do
17 not know if they have a filter failure. You agree with that?

18 A I believe the majority of complications are asymptomatic.

19 Q Meaning if patients don't know about them and don't go to
15:36:11 20 their doctors, there's no chance it will get reported to the
21 MAUDE database; right?

22 A Yeah. If it's not reported, then, yeah.

23 Q And that's a problem with the MAUDE database, it's
24 underreported. You know that.

15:36:29 25 A I've heard that the MAUDE database can be underreported.

15:36:32 1 How much, I'm not sure.

2 Q All right. Thank you.

3 THE COURT: All right. Sir, you can step down.

4 Thank you.

15:36:51 5 MR. CLARK: Your Honor, the plaintiff would call
6 Jason Greer, and the plaintiff would move into evidence trial
7 Exhibits 1912 and 992.

8 MS. HELM: No objection.

9 THE COURT: Those are admitted.

15:37:12 10 (Exhibits 1912 and 992 admitted.)

11 MR. CLARK: May I give the jury the -- there are only
12 two, so I'll give the numbers, if that's okay, Your Honor.

13 THE COURT: This is video?

14 MR. CLARK: This is video deposition; correct.

15:37:22 15 THE COURT: All right.

16 MR. CLARK: Ladies and gentlemen, trial Exhibit 1912
17 is Deposition Exhibit 7.

18 Trial Exhibit 992 is Deposition Exhibit 12.

19 THE COURT: 12?

15:37:35 20 MR. CLARK: One two. Yes. 12.

21 May I read the summary of this witness?

22 THE COURT: You may.

23 MR. CLARK: Jason Greer graduated from the University
24 of Mississippi and became a sales representative at Bell South
15:37:48 25 Mobility in 1991 and worked for two other companies doing

15:37:53 1 sales until he joined Bard Peripheral Vascular in 1999 as a
2 sales representative. In 2005 he became a district manager.
3 Throughout his time at Bard he sold Bard's IVC filters.
4 Mr. Greer left Bard in 2007 and currently works for another
15:38:10 5 medical device manufacturer.

6 (Video testimony of Jason Greer played.)

7 MR. CLARK: At this point, Your Honor, the plaintiff
8 would call Janet Hudnall, also via video deposition, and would
9 move into evidence the following exhibits:

15:47:17 10 545. 1053. 1336. 1337. 1339, which is subject to
11 redaction. 1594, also subject to redaction.

12 MS. HELM: No objection, Your Honor, subject to
13 redactions.

14 THE COURT: Those are admitted.

15:47:41 15 (Exhibits 545, 1053, 1336, 1337, 1339, 1594 admitted.)

16 MR. CLARK: May I approach to provide the jurors a
17 cheat sheet?

18 THE COURT: Yeah, go ahead and give it to Traci and
19 she'll hand it out.

15:48:12 20 MR. CLARK: May I be permitted to read the background
21 summary?

22 THE COURT: Yes.

23 MR. CLARK: Janet Hudnall has a degree in industrial
24 engineering from the Georgia Institute of Technology and an
15:48:21 25 MBA from ASU. She began working for what became Bard

15:48:24 1 Peripheral Vascular in June of 1998 as a product development
2 engineer and was promoted to senior product manager in 2002,
3 and marketing manager in 2004.

4 As marketing manager, Ms. Hudnall managed marketing
15:48:40 5 activities of BPV's IVC product filter line and was involved
6 in the launch of both the Recovery filter the G2 filter.

7 Ms. Hudnall left BPV in 2008 and since then has
8 worked in marketing for several medical device manufacturers.

9 And I would note for the jury that there is a portion
15:48:58 10 of this deposition where the audio is somewhat muffled. That
11 is a problem with the tape and we do apologize for any
12 inconvenience.

13 (Video testimony of Janet Hudnall played.)

14 THE COURT: Counsel, let's stop the deposition.

15:14:36 15 All right, ladies and gentlemen, we've reached 4:15
16 so we're going to break for the day.

17 Thank you for your attention today.

18 Members of the jury, let me just remind you we are
19 reconvening Tuesday morning at 9 o'clock. Over the long
16:14:49 20 weekend, please be sure not to do any research or talk to
21 anybody about the case.

22 We'll plan to see you Tuesday morning. Have a nice
23 weekend. Thank you all.

24 (The jury exited the courtroom.)

16:15:12 25 THE COURT: Counsel, do you know how you're

16:15:13 1 allocating deposition video time?

2 MS. HELM: Yes, Your Honor. Mr. Clark, and I have
3 conferred. The total, including Ms. Hudnall, is 66 minutes --
4 you don't want me to include her?

16:15:24 5 THE COURT: Well, through now or including on Monday?

6 MS. HELM: There's two minutes left of that video.

7 THE COURT: Okay.

8 MS. HELM: 66 minutes for the plaintiff, 25 minutes
9 for the defendant.

16:16:22 10 THE COURT: All right. Counsel, as of the end of
11 today plaintiff has used 15 hours and 41 minutes.

12 Defense has used four hours and one minute.

13 We will plan to see you Tuesday morning at 8:30.

14 MR. CLARK: Your Honor, I need to correct one
16:16:39 15 statement I made to the Court at the sidebar relating to the
16 filterlaw discussion we had about the Dear To Whom It May
17 Concern letter.

18 I believe I indicated to the Court as part of my
19 argument that I thought the filterlaw website came online
16:16:56 20 after the date of the June 29, 2009, letter. I was mistaken
21 about that. I had reviewed a document and I must have been
22 confused because we were talking about the Denali in August of
23 2009. I went and re-reviewed the document after Mr. North
24 pointed out he believed it actually came online in December of
16:17:13 25 2008. The document I reviewed was February 2009, and I do

16:17:18 1 apologize to the Court and the parties about that.

2 I will note that that was not my principal argument.

3 I still believe that this document opens a whole can of worms

4 with respect to class actions, television ads and everything,

16:17:33 5 but I did want to correct that statement, and I thank

6 Mr. North for bringing it to my attention.

7 THE COURT: Okay. Does that change anything?

8 MR. NORTH: No, Your Honor.

9 MR. ROGERS: No, Your Honor.

16:17:44 10 THE COURT: Okay. We'll see you all Tuesday morning.

11 Thank you all.

12 (End of p.m. session transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 18th day of May, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter